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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[redacted]

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of Micronucleus Assay on P91-391

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## I. CONCLUSION

The chemical tested for P91-391 is stated to not be a chromosome mutagen in vivo in mice in the micronucleus assay by oral gavage. The report is inconclusive due to the lack of supporting numerical data. Also, if this were to be exposure-based testing, the intraperitoneal route of administration should be employed.

## II. BASES FOR THE CONCLUSION

The chemical tested for P91-391, identified as "CL 959" was evaluated for its ability to induce chromosomal effects in vivo in the mouse micronucleus assay. It is Study No. 6796 MAS and is dated December 5, 1990. The French laboratory conducting the assay was not identified.

The chemical was evaluated for its ability to induce micronucleated polychromatic erythrocytes (PCEs) in Swiss mice. Animals were exposed to a single oral administration of the test chemical. The dose level administered is given as 2000 mg/kg in the body of the report (p. 8), but as 500 mg/kg in the summary (p. 5) and in the discussion of preliminary toxicity data (p. 10). The 500 mg/kg dose is adequate. The vehicle was 1% carboxymethylcellulose. Animals were evaluated for micronuclei 24, 48 and 72 hours after exposure. For each treatment group, 5 males and 5 females were dosed. Concurrent negative (vehicle) and positive controls were also evaluated.

1000 PCEs per animal were evaluated for micronuclei, and the NCE/PCE ratio determined. The report states that there were no significantly elevated frequencies of micronucleated PCEs for any treatment condition with the test chemical, no significant effect on NCE/PCE ratio, and an appropriate response from the positive control. However, no numerical data or tables were included to support these conclusions. The study cannot be properly evaluated without supporting data.

The substance is stated to not be a chromosome mutagen in vivo in mice in the micronucleus assay by oral gavage. The report is inconclusive due to the lack of supporting numerical data. Also, if this were to be exposure-based testing, the intraperitoneal route of administration should be employed.